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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,895	05/14/2001	Yuanxiang Tao	01107.00130	6167

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

# Office Action Summary

Application No.

09/853,895

Applicant(s)

TAO ET AL.

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on 23 December 2002.

2a) ☐ This action is **FINAL**.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) 1-25, 28-31 and 34-65 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 26, 27, 32 and 33 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 08-29-2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some \* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election without traverse of Group X, claims 26, 27, 32 and 33 in Paper No. 10 is acknowledged.

Claims 1-25, 28-31 and 34-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 27, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 33 are indefinite because they are dependent upon a non-elected claim.

Claims 26, 27, 32 and 33 are indefinite because they recite non-elected subject matter.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26, 27, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 27, 28, 32 and 33 are drawn to methods that require the use of agents that inhibit the interaction of PSD93 with NMDA and bind to a PDZ domain in vivo and further do not cause cardiovascular or respiratory depression and do not impair motor function. The agents used in the claimed methods would encompass a very broad genus of compounds of variant structure, including, for example, structurally unrelated antibodies binding to either PSD93 or NMDA, structurally unrelated proteins or peptides which bind to either PSD93 or NMDA, structurally unrelated aptamers, various small organic and inorganic molecules, etc.

The specification describes halothane as inhibiting the PDZ domain interaction between PSD-93 and NMDA receptors (see for example, page 23, Example 10). The specification does not describe any other agent that inhibits the interaction of PSD93 and NMDA, and which further have the characteristics wherein the agent does not cause cardiovascular or respiratory depression and does not impair motor function. The prior art does not describe agents which inhibit the interaction of PSD93 and NMDA, and which further have the characteristic wherein the agents do not cause

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cardiovascular or respiratory depression and do not impair motor function. The specification provides insufficient written description to support the genus of agent required to practice the methods encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of halothane, the skilled artisan cannot envision the detailed chemical structure of the agents required to practice the claimed methods, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The one species of agent specifically disclosed, halothane, is not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 27, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Mason et al. (Anesthesiology, 1996, Vol 84, No. 5, p 1205-1214).

Mason et al. disclose intrathecally-administering halothane to rats to relieve pain, for example, pain induced by tail clamping. Mason et al. do not state that halothane inhibits the interaction of PSD93 and NMDA by binding the PDZ domain, however, the instant application discloses halothane as an agent of the invention (see for example page 23, Example 10). The method disclosed by Mason et al. would inherently interfere with the binding of PSD93 and NMDA by halothane binding to the PDZ domain. Therefore, Mason et al. anticipates claim 26, 27, 32 and 33.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
March 7, 2003

*Karen A. Lacourciere*  
KAREN LACOURCIERE  
PATENT EXAMINER